

Applicant notes with appreciation the withdrawal of the rejections under 35 U.S.C. § 112 set forth in the Office Action dated June 13, 1994, Paper No. 12.

In the Office Action, the Examiner has rejected claims 1-7 and 9-14 under 35 U.S.C. § 112, second paragraph. While not acceding to the Examiner's position, solely in an effort to expedite prosecution, applicant has amended claim 1 as suggested by the Examiner, i.e., to recite "Factor VIII:C" after "containing". Accordingly, this ground of rejection is now moot and withdrawal thereof is respectfully requested.

The Examiner has also rejected claims 1-7, 9-12 and 14 under 35 U.S.C. § 103 over Myers et al. ("Myers"). Applicant traverses this rejection.

Initially, applicant respectfully notes that this rejection is stale. Myers, the reference upon which the Examiner has relied, was previously cited as an anticipatory reference against the pending claims under 35 U.S.C. § 102(a). In the prior Office Action, Paper No. 12, however, this rejection was withdrawn and, significantly, no rejection for obviousness issued. It therefore hardly seems proper for the Examiner to revive Myers now that all of the rejections of record have been overcome.

The Examiner is reminded of the caveat in the Manual of Patent Examining Procedure that "it is to the interest of the applicants as a class as well as to that of the public that prosecution of a case be confined to as few actions as is consistent with a thorough consideration of its merits." M.P.E.P. § 706.07. Indeed, the Manual specifically counsels

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against "[s]witching . . . from one set of references to another . . . in rejecting in successive actions claims of substantially the same subject matter . . . ." M.P.E.P. § 706.07.

Such is precisely the situation here -- the Examiner once relied on Myers as prior art for rejecting the pending claims, but subsequently withdrew this rejection and issued different rejections. Now, however, following a response by applicant to those rejections, the Examiner has again elected to rely on Myers for rejecting claims which are substantially the same as those originally rejected over this reference.

Further, the presently claimed invention has already been clearly distinguished from Myers. More specifically, as noted in the Preliminary Amendment filed September 9, 1993, Myers does not teach or suggest a stabilized solution having factor VIII:C activity wherein the specific factor VIII:C activity is at least 1000 IU/mg.

Rather, while Myers does disclose a process for preparing factor VIII:C compositions, those compositions have a specific activity no higher than  $4.4 \pm 0.9$  IU/mg protein. As may be easily ascertained, this level is nearly two orders of magnitude lower than that of the presently claimed invention!

The Examiner's assertion to the contrary, viz., that 185 IU of factor VIII:C activity per liter of starting plasma is "at least equivalent" to the claimed yield, is totally without merit. The yield in Myers to which the Examiner refers is, in fact, related to the recovery of factor VIII:C, i.e., how much factor VIII:C was obtained relative to the amount of plasma used. See

Myers, p. 145, Table 2. Conversely, specific activity, as recited in the pending claims, is related to the purity of the factor VIII:C obtained and has nothing to do with the amount of factor VIII:C recovered by the process. In other words, the Examiner has erroneously equated a quantitative value with a qualitative value.

In sum, there simply is no suggestion in Myers of a stabilized factor VIII:C solution having anywhere near the level of specific activity presently claimed, much less any direction as to how to obtain such a solution. Accordingly, for at least this reason, the Examiner's position is untenable.

Additionally, with respect to at least those claims directed to pharmaceutical preparations (i.e., claims 9-11), the final factor VIII solution described by Myers as being suitable for clinical use contains practically no detergent. In particular, following virus inactivation, the detergent (Tween 80) was removed to a final content of 15-35 ppm. See Myers, p. 144.

Indeed, one of Myers' goals was optimization of recovery of factor VIII:C while reducing detergent levels to clinically acceptable values. Thus, Myers would lead the skilled worker away from a pharmaceutical preparation containing a factor VIII:C solution which included a detergent.

For these reasons, withdrawal of the outstanding rejection is proper and requested.

In view of the foregoing amendments and remarks, claims 1-7 and 9-14 are in condition for allowance. Withdrawal of the

outstanding rejection and prompt allowance of this application are therefore respectfully solicited.

If there are any fees due in connection with the filing of this paper, please charge the fees to Deposit Account No.

06-0916. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to Deposit Account No. 06-0916.

Respectfully submitted,

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